REMARKS

The foregoing amendments are responsive to the September 10, 2007 Office Action. Applicant respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Amendments to the Specification

The specification has been amended as requested by the Examiner.

Response to Rejection of Claims 39-43 and 45-47 Under 35 U.S.C. 112, first paragraph

The Examiner rejected Claims 39-43 and 45-47 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Applicant directs the Examiner to related Figures 17A-B and to paragraphs [0146-0148] of the specification. Figure 17A illustrates the use of fiduciary markers synchronizing the fluoroscopy image (see paragraph [0056]) and then Figure 17B illustrates the use of the fiduciary markers in performing a pacemaker electrode implementation (see paragraph [0057]). The specification teaches (emphasis added):

> **[0146]** Figure 17A illustrates forming a stereotactic frame in support of position definition of the catheter tip relative to the frame. This method utilizes fiduciary markers formed as an approximate cube.
>
> The solution presented herein is a method of capturing the Fluoroscopic Image generated by the x-ray Apparatus and/or ultrasonic imaging technique to create Referential Markers for synchronizing the image of the catheter tip or guide wire, which is generated by the GCI apparatus and superimpose that image onto the fiduciary markers which are represented digitally and are linked dynamically as to create one image which moves in unison with the area of interest. For example, **the beating heart and its cardio-output, the pulmonary expansion and contraction, or a spasm of the patient, can be dynamically captured and**

linked together as to achieve unison motion between the catheter's tip and the body's organ in question.

[0147] Figure 17A further illustrates the image capture technique of superimposing the fiduciary markers 700A1, 700A2, 700A3, 700A4, 700B1, 700B2, 700B3, and 700B4 onto the fluoroscopic/ultrasonic image, generated as shown in image 17. The scheme provided identifies the dynamic location of the catheter tip 377 with reference to the fluoroscopic/ultrasonic image. The referential frame formed by the fiduciary markers 700Ax defines the catheter's tip position relative to the stereotactic frame. Furthermore, by employing a technique of geometric projection this method provides for a synchronized image-capture relative to catheter tip, 377 thereby affording the superimposition of the fluoroscopic/ultrasonic image relative to **both the fiduciary markers and the catheter tip on a dynamic basis, hence, providing position definition with a frame of reference.**

[0148] Figure 17B illustrates the implantation of cardiac pacemaker 801 with electrodes as shown, placed in area relative to the S.A. Node 802, A.V. Node 803, and a bundle of His 804. Further illustrated are the right and left bundle branches 805. Pacemaker implantation is essential for the survival of patients with heart rhythm or electrical conduction disturbances. This procedure is performed by the implantation of a small electrode **in the heart cavity wall (ventricle or atrium)**. The other end of the electrode is attached to an electronic device 801 which is implanted under the chest skin and which generates stimulation pulses to simulate the heart rhythm. Similar devices apply electrical shock when life threatening heart electrical disturbances are detected by the electrodes (Automatic Implantable Cardiac Defibrillator (AICD). These electrodes are placed through a vein by pushing and manipulating under fluoroscopy. Through the use of the apparatus proposed GCI 501 and guidewire 379 fitted with magnetic tip 381 is used to carry and place the electrodes of pacemaker 801 in its proper position by using the method and apparatus described in this patent. By employing the fiduciary markers 700A1, 700A2, 700A3, 700A4, 700B1, 700B2, 700B3, and 700B4 the physician navigates the guidewire 379 through the heart lumen while having a continuous dynamic referential frame identifying the guidewire tip 381 and as shown in 17 and further illustrated by figure 17A. Many times, the manipulation to place the electrodes in a proper position is difficult and the results are sub-optimal due to anatomical variations. The use of the proposed apparatus 501 provides simplicity in performing such a complex operation while the physician is capable of moving, pushing, and placing the electrodes of pacemaker 801 in its precise anatomical position without compromise due to the inability of navigating,

> guiding, controlling, and imaging the movement of the guidewire and the pacemaker electrodes accurately.

As shown in the quoted section above, the specification clearly teaches synchronizing the dynamic motion of the catheter tip with the wall of a heart chamber (e.g., ventricle or atrium). Accordingly, Applicant requests the Examiner to withdraw the rejection of Claims 39-43 and 45-47 under 35 U.S.C. 112, first paragraph.

Response to Rejection of Claims 39, 42 and 45 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 39, 42 and 45 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) in view of Nowlin et al. (US 6,459,926) and Wang et al. (US 5,971,976).

Blume teaches a device for specifying the orientation of a magnetic field. Nowlin teaches a system that maintains a fixed relationship between an input handle end and a surgical end effector. Combining Blume with Nowlin does not yield a system with a tactile feedback and a controller that includes a correction input to allow the system controller to compensate for a dynamic position of a wall of a heart chamber such that a surgical tool moves substantially in unison with said wall. Wang teaches attaching a stabilizing device "to minimize heart motion at a given location, sense and measure any residual motion in the area proximate to the area where the heart motion has been minimized (see column 3 at lines 19-23, and Claim 1).

By contrast, Applicant teaches and claims a system that provides synchronization without minimizing movement of the heart. As shown in the specification and figures the claimed invention does not use a stabilizing device, thus the heart is free to produce its natural motion. The catheter tip is synchronized with that motion by using data from an auxiliary device that senses the position of the heart relative to a frame of reference.

Regarding Claim 39, the cited prior art does not render obvious a controllable magnetic field source having a first cluster of electromagnet poles and a second cluster of electromagnet

poles, the first cluster of poles substantially opposed to the second cluster of poles, a tool having a distal end responsive to the magnetic field, one or more sensors configured to sense a current position of the distal end; a system controller for controlling the magnetic field source to control a movement of the distal end according to a feedback calculation wherein the system controller is configured to compute a position error comprising a difference between a desired position of the distal end and the current position of the distal end; and a Virtual Tip that provides tactile feedback to an operator, wherein an amount of tactile feedback is computed by the system controller at least in part according to the position error, wherein a correction input to the desired position is computed based on data from an auxiliary device relative to a frame of reference, such that the system controller compensates for a dynamic position of a wall of a heart chamber such that the distal end moves substantially in unison with the wall wherein a correction input to said desired position is computed based on data from an auxiliary device, such that said system controller compensates for a dynamic position of a wall of a heart chamber such that said distal end moves substantially in unison with a natural motion of said wall.

Regarding Claim 42, the prior art does not render obvious the apparatus of Claim 39, where the apparatus further includes an operator interface unit.

Regarding Claim 45, the prior art does not render obvious the apparatus of Claim 39 with a Virtual Tip Calibration Fixture.

Applicant asserts that Claims 39, 42 and 45 are allowable over the prior art, and Applicant requests allowance of Claims 39, 42 and 45.

Response to Rejection of Claims 40 and 41 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 40 and 41 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Nowlin et al. (US 6,459,926), and Wang et al. (US 5,971,976), as applied to Claims 39, 42 and 45 above, and further in view of Solf et al. (US 6,587,709). Blume and Nowlin are discussed above.

Regarding Claim 40, the prior art does not render obvious the apparatus of Claim 39, where the distal end includes one or more piezoelectric rings.

Regarding Claim 41, the prior art does not render obvious the apparatus of Claim 39, where the distal end includes one or more piezoelectric rings for providing sensor data to a system controller. Neither Solf, nor the other cited references, teach or render obvious providing sensor data from one or more piezoelectric rings to a system controller.

Applicant asserts that Claims 40 and 41 are allowable over the prior art, and Applicant requests allowance of Claims 40 and 41.

Response to Rejection of Claim 43 Under 35 U.S.C. 103(a)

The Examiner rejected Claim 43 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Nowlin et al. (US 6,459,926), and Wang et al. (US 5,971,976) as applied to Claims 39, 42 and 45 above, and further in view of Hastings et al. (US 6,148,823). Hastings teaches a first pole connected to a second pole by a magnetic material. The cited references do not teach or render obvious a first cluster of electromagnet poles connected to a second cluster of electromagnet poles by a magnetic material.

Regarding Claim 43, the cited prior art does not make obvious the system of Claim 39 wherein the first cluster of poles is connected to the second cluster of poles by a magnetic material.

Applicant asserts that Claim 43 is allowable over the prior art, and Applicant requests allowance of Claim 43.

Response to Rejection of Claim 46 and 47 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 46 and 47 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Nowlin et al. (US 6,459,926) and Wang et al.

(US 5,971,976) as applied to Claims 39, 42 and 45 above, and further in view of Haynor et al. (US 6,129,668) and Tanabe et al. (US 5,550,469).

Regarding Claim 46, the prior art does not render obvious the apparatus of Claim 39, further including a communication controller, a calibration fixture, and one or more temperature sensors.

Regarding Claim 47, the prior art does no render obvious the apparatus of Claim 39 wherein said one or more sensors comprise one or more temperature sensors paired with one or more magnetic sensors.

Applicant asserts that Claims 46 and 47 are allowable over the prior art, and Applicant requests allowance of Claims 46 and 47.

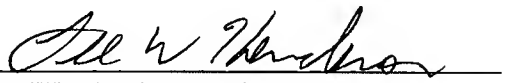
Summary

Applicant respectfully asserts that Claims 39-43 and 45-47 are in condition for allowance, and Applicant request allowance of Claims 39-43 and 45-47. If there are any remaining issues that can be resolved by a telephone conference, the Examiner is invited to call the undersigned attorney at (949) 721-6305 or at the number listed below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: October 23, 2007

By: 

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